Remarks

Reconsideration and withdrawal of the rejection set forth in the above-mentioned Official Action in view of the foregoing amendments and the following remarks are respectfully requested.

Claims 1-77 remain pending in the application, with Claims 1, 13, 24, 33, 45, 56, 65, 70 and 75 being independent. Claims 1, 13, 24, 33-65, 70 and 75 have been amended herein.

Claims 33, 45 and 56 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Without conceding the propriety of this rejection, and solely to advance prosecution, Applicants have amended these claims to recite a combination including the container. Reconsideration and withdrawal of the § 112 rejection are respectfully requested.

Claims 1-77 were rejected under 35 USC § 103(a) as allegedly being obvious over U.S. Patent No. 6,209,591 (Taggart). This rejection is respectfully traversed.

The present invention relates to a method of and an apparatus for sterilization and/or sanitization a container. In one aspect, as now recited in independent Claims 1, 13, 24, 33, 45, 56, 65, 70 and 75, the method comprises, *inter alia*, a sterilant vapor generating step; the apparatus comprises, *inter alia*, a generator of sterilant vapor, with the sterilant being maintained in a vapor state. Compared to liquid sterilant or liquid/vapor sterilant, the use of completely vapor state sterilant offers three major advantages. First, application of vapor state sterilant allows immediate and uniform contact of the sterilant with the microorganisms in the container. As a result, when equivalent amounts of vapor state sterilant and liquid state sterilant are applied to a

container, the time required to cause destruction of microorganisms is reduced. The difference is so great that treatment of containers by fully vaporized peroxide can be accomplished in less time and with less peroxide than is possible by application methods such as employed by Taggart. Second, the present invention provides significant avoidance of costs. Smaller quantities of peroxide per container measurably reduce the operating costs associated with the use of this expensive chemical and the need to remove only small amounts of peroxide from bottles reduces the size or amount of capital-intensive equipment. Third, the reduction in the amount of sterilant applied to each container in turn reduces the amount of sterilant absorbed by the container. Thus, the amount of residual sterilant left in a container following the purging step is also reduced when vapor state sterilant is used.

In another respect, as now recited in independent Claim 75, the method of sterilizing and/or sanitizing a non-heat-set PET container comprises, *inter alia*, generating hydrogen peroxide sterilant vapor; discharging the generated sterilant vapor into the container, and purging the container of the discharged sterilant with heated gas. The steps are controlled so that the amount of sterilant in the container at 24 hours after the purging step is reduced to a predetermined amount Z, by satisfying the equation $Z = (0.030 \times a/b) - (0.043 \times T_1) - (0.040 \times c/b) - (0.075 \times T_2) + 15.747$, where a is the mass of discharged sterilant vapor (mg), b is the container volume (l), c is the volume of purging gas (l), T_1 is the temperature of the discharged sterilant vapor (°F), and T_2 is the temperature of the purging gas (°F).

As discussed in paragraph [0005] of the specification, due to their unique molecular structure, it is difficult to remove residual sterilant from polymer based

containers such as non-heat-set PET containers. Hydrogen peroxide trapped in the polymer matrix is not readily removed with the hot air flush. Although this can be quite stable for several minutes to hours, when a fluid product is introduced into the container, the hydrogen peroxide moves from the polymer matrix into the body of the fluid product. As several studies have suggested that hydrogen peroxide may be carcinogenic, sterilization and/or sanitization of PET containers with hydrogen peroxide poses potential health risks to consumers. The inventors of the present invention recognized the unique problem associated with the sterilization/sanitation of PET containers. The inventors discovered that if the amount of residual sterilant satisfies the equations recited in Claim 75, the residual hydrogen peroxide at 24 hours after the purging step can be less than the 0.5 ppm limit required by the FDA.

In another respect, reduction of Bacillus spores in the container by a predetermined amount X (log) and reduction of yeast ascospores in the container by a predetermined amount Y (log) is effected by controlling the process steps to satisfy the equations recited in independent Claims 65 and 70, respectively. The inventors of the present invention recognized the complex relationship between all components of the container sterilization process, and discovered that the parameters can be combined in a mathematically precise manner to yield the targeted reduction of viable spores of Bacillus or viable ascospores of yeast. The inventors were able to formulate the mathematical equations recited in Claims 65 and 70 only after exhaustive experimentation. Accordingly, it is not mere optimization as suggested by the Examiner.

Taggart relates to an apparatus and method for providing container product filling in an aseptic processing apparatus. In the method of Taggart, liquid hydrogen

peroxide or hydrogen peroxide in the form of a heated vapor fog is used. To one skilled in the art, a heated vapor fog is a mixture of vapor and fog-sized aerosol particles obtained during disintegration of liquid. Taggart also states that "droplet size occurring on the interior surface 119 of the bottles 12 is in the range of about 300 to 500 micrometers." (See column 10, lines 15-17). The size of the droplets clearly shows that the sterilant is applied in a form other than completely vapor. In addition, the use of the term "spray" in describing hydrogen peroxide delivery suggests that all or at least a large portion of the sterilant delivered in Taggart is in liquid form.

Accordingly, Taggart fails to disclose or suggest that the use of a sterilant vapor, the sterilant being maintained in a completely vapor state, as is recited in independent Claims 1, 13, 24, 33, 45, 56, 65, 70 and 75.

Taggart also fails to disclose or suggest effecting a reduction of microorganisms by controlling the vapor generating, vapor discharging and purging steps so as to satisfy the equations of independent Claims 65 and 70. The Examiner suggests that it would have been obvious "to determine any remaining parameters such as container size, mass of sterilant and humidity." However, one would have to recognize the relationship of those parameters to their desired result to determine desired values of such parameters. Such is not disclosed or suggested in Taggart.

In addition, as Taggart fails to recognize the hydrogen peroxide trapping problem associated with the sterilization/sanitation of PET containers, Taggart does not disclose or suggest that 24 hours after the purging step, the hydrogen peroxide residual in non-heat-set PET containers should be (or is) less than the 0.5 ppm limit required by the FDA. Accordingly, Taggart also fails to disclose or suggest reduction of the sterilant in

the PET container to a predetermined amount Z (mg/l) at 24 hours after said purging step is effected by satisfying the equation $Z = (0.030 \times a/b) - (0.043 \times T_1) - (0.040 \times c/b) - (0.075 \times T_2) + 15.747$, as is recited in independent Claim 75.

Thus, Taggart fails to disclose or suggest important features of the present invention recited in the independent claims.

Thus, independent Claims 1, 13, 24, 33, 45, 56, 65, 70 and 75 are patentable over the citations of record. Reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

For the foregoing reasons, Applicants respectfully submit that the present invention is patentably defined by independent Claims 1, 13, 24, 33, 45, 56, 65, 70 and 75. Dependent Claims 2-12, 14-23, 25-32, 34-44, 46-55, 57-64, 66-69, 71-74, 76 and 77 are also allowable, in their own right, for defining features of the present invention in addition to those recited in their respective independent claims. For example, Claim 35 recites positioning a nozzle just below the shoulder of the container. Although the Examiner suggests in Fig. 10 of Taggart nozzle 122 is located just below the shoulder of the bottle, such is not shown in the figure. Individual consideration of the dependent claims is requested.

Applicants submit that the present application is in condition for allowance. Favorable reconsideration, withdrawal of the rejection set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 530-1010. All correspondence should continue to be directed to our below-listed address.

Respectfully submitted,

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